DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2003N–0016]

## Medical Devices; Revised MedWatch Forms; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the revised MedWatch Voluntary Reporting Form (FDA Form 3500), the revised Mandatory Reporting Form (3500A), and the respective instructions for each form.

**DATES:** The revised MedWatch forms are effective immediately. The forms were approved by the Office of Management and Budget (OMB) on September 12, 2003 (see 68 FR 58691, October 10, 2003); however, reporters may continue to use the prior version of Forms 3500 and 3500A until *[insert date 6 months after date of publication in the* **Federal Register].**

**FOR FURTHER INFORMATION CONTACT:** Howard **A.** Press, Center for Devices and Radiological Health (HFZ–531), 1350 Piccard Dr., Rockville, MD 20850, 301–827–2983.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 303 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) amended the Federal Food, Drug, and Cosmetic Act (the act) to require FDA to modify Forms 3500 and 3500A, the MedWatch voluntary and mandatory reporting forms respectively, to facilitate the reporting, by user

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facilities or distributors, of adverse events involving single-use devices (SUDs) that have been reprocessed for reuse in humans. The following two questions were added to the revised MedWatch forms: (1) Is this a single-use device that was reprocessed and reused on a patient? and (2) If yes, enter the name and address of the reprocessor.

**11. Comments**

In the **Federal Register** of April 29, 2003 (68 FR 22716), FDA published a notice requesting public comment on the information collection provisions. FDA received several comments.

One comment stated that there are no affirmative mechanisms that would allow original equipment manufacturers (OEMs) to detect when a single-use device had been reprocessed.

FDA disagrees with this comment. We believe that there are several ways an OEM can ascertain whether a single-use device has been used and reprocessed.

Under § 803.50(b) (21 CFR 803.50(b)), the medical device reporting regulation (MDR), manufacturers are obligated to report information that is reasonably known to them. The information that is reasonably known to a manufacturer includes information that: (1) Can be obtained by contacting the user facility, importer, or other initial reporter; (2) is in the manufacturer's possession, or (3) can be obtained by analysis, testing, or evaluation of the device (see § 803.50(b)).

If an OEM has reason to believe that the SUD has been reprocessed, there are a number of steps the OEM can take to follow up. The OEM can contact either the user facility or the reporter to determine if the SUD was reprocessed and reused on a patient (question D8 of both Forms 3500 and 3500A). This information should be readily available to a user facility since the practice of

reusing reprocessed SUDs generally requires the user facility to have in place a written policy, procedure, or contract that supports this practice. In all cases, FDA recommends that requests for information to user facilities or individual reporters be in writing so that the OEM has documentation about its reasonable efforts to determine if the SUD was reprocessed and reused on a patient. In addition, OEMs may already be in possession of information, such as reports from their sales representatives, which will help them determine if an SUD was reprocessed. An OEM can conduct testing and analysis of any SUD that has been returned to them to try to get additional information about whether the device was reprocessed.

FDA believes that there may be occasional situations where an OEM has exhausted all reasonable mechanisms to determine whether the SUD has been reprocessed and is still unable to determine its status. In that event, the OEM should enter ''UNK'' (unknown) in block D8 and report in block H10 of the 3500A form that it is unable to determine if the suspect device was reprocessed and reused on a patient. The OEM also should describe in block H10, the steps the OEM took to try to obtain the information, including any responses from user facilities or other reporters. The OEM's MDR files should include supporting documentation for what has been reported in block H10.

FDA wishes to emphasize that it considers any entity that reprocesses an SUD for reuse in humans to be the manufacturer of the reprocessed SUD and, accordingly, subject to all the regulatory requirements currently applicable to OEMs, including the responsibility for MDR reporting. Therefore, if an OEM determines that an SUD has been reprocessed for reuse in humans, the OEM has no further MDR obligation for the device involved in this event. The OEM should forward all of the information concerning the event to FDA and state

in the cover letter that the SUD was reprocessed. In that case, the SUD is not the OEM's device, but rather is now the reprocessor's device (see § 803.22(b)(2) (21 CFR 803.22(b)(2)).

One comment referred to an apparent conflict between the amended section 303 of MDUFMA and MDR (§ 803.52(f)(11)(i) and (f)(11)(iii)), which requires manufacturers to provide corrected and/or missing data on the MedWatch form. If the data are not provided, the manufacturer is required to explain why the information was not provided and the steps that were taken to obtain the information.

FDA disagrees with this comment. We do not believe that there is a conflict between section 303 of MDUFMA and the MDR regulation. The purpose of section 303 of MDUFMA was to facilitate the reporting of information relating to reprocessed SUDs. We believe that this information will come primarily from user facilities, which generally have in place policies, procedures, or agreements supporting the reuse of reprocessed SUDs. As stated previously, once an OEM determines that the SUD has been reprocessed by either contacting the user facility, reviewing information in the firm's possession, or by testing or evaluating the device itself, the OEM is no longer responsible for reporting the event or any information related to the event.

A comment addressed the redesign of both forms FDA 3500 and FDA 3500A. The comment suggested revising sections F and H of the mandatory MedWatch form (FDA Form 3500A) and section D of the voluntary MedWatch Form (FDA Form 3500).

FDA disagrees with this comment. The MedWatch forms are used by all entities that report to the agency. However, the two new questions pertain only to medical devices. Consequently, we redesigned the forms to limit the changes

to those required under MDUFMA. The instructions for completing the revised Forms 3500 and 3500A have been modified accordingly and are available on FDA's MedWatch Web site (see **111. Availability of Forms).**

Some comments requested to extend the deadline to comply with the revised forms. Initially, one comment asked that manufacturers be given until September 30, 2005, to comply with the revised form. A later comment suggested providing a I-year interim period for industry to modify their reporting systems.

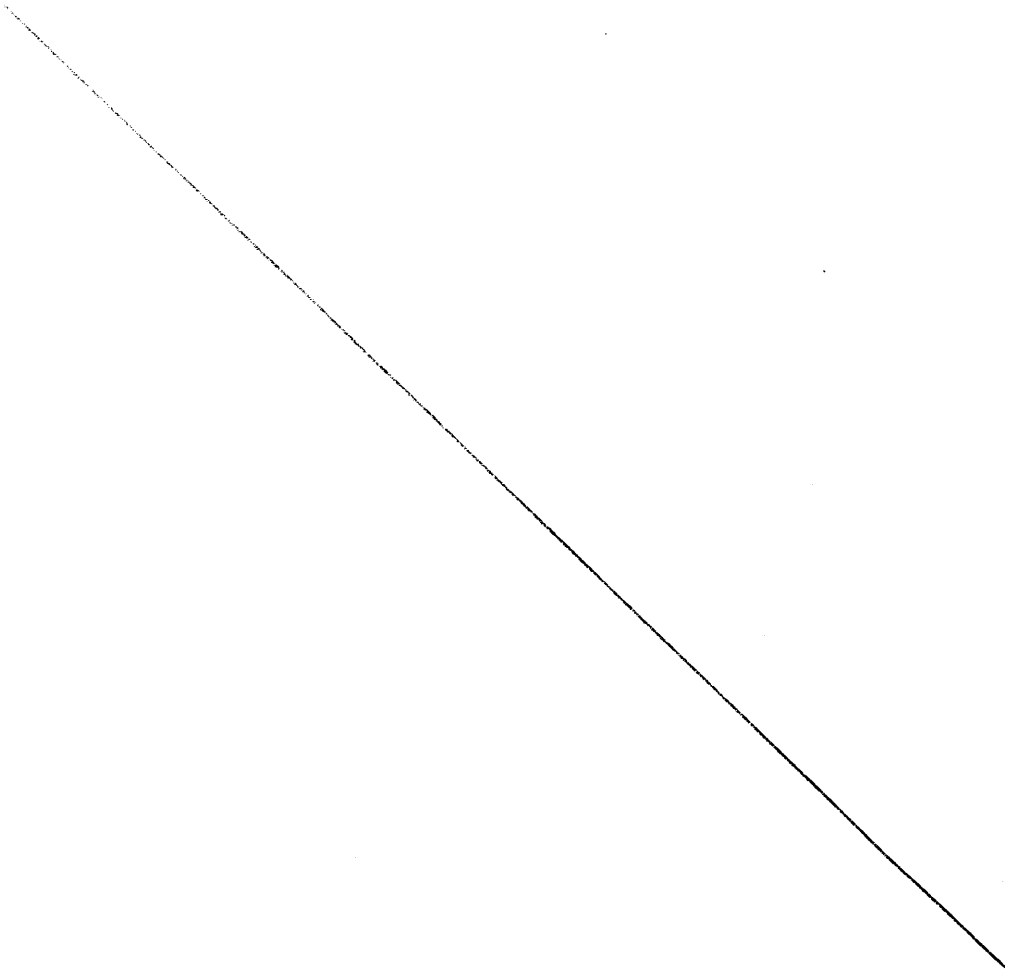
FDA partially agrees with the comments. Congress required FDA to modify the MedWatch forms by April 26, 2003. We agree that a reasonable period of time is needed for medical device reporters to incorporate the two new questions into their reporting systems. In the October 10, 2003, notice, FDA announced that OMB approved the information collection for the MedWatch program. At FDA's request, OMB approved the continued use of the previous forms for 6 months to allow time for the reporters to make the necessary changes to their computerized systems.

During this transitional period FDA will accept both the newly effective Forms 3500 and 3500A and the prior versions of the forms. Information concerning the reuse of the product (new question D8) and the name and address of the reprocessor (new question D9) can be provided in section H10 on the prior version of form 3500A (OMB approval date, November 2002). Reporters may continue to use the prior version of Forms 3500 and 3500A until [*insert date 6 months after date of publication in the* **Federal Register].** During this 6-month period, the prior versions and the instructions will be available on FDA's Center for Devices and Radiological Health MDR Web site at *http://www.fda.gov/cdrh/mdr/mdr-forms.html.*

**111. Availability of Forms**

The newly revised MedWatch forms are available at FDA Form 3500 *http://www.fda.gov/medwatch/safety/3500.pdf* and FDA Form 3500A *http://www.fda.gov/medwatch/safety/3500a.pdf.*

The instructions for the revised forms are available at FDA Form 3500 *http://www.fda.gov/medwatch/report/consumer/instruct.htm* and FDA Form 3500A *http://www.fda.gov/medwatch/report/instruc.htm.*



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Dated: Jan 30, 2004

January 30, *2004.*

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